

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3392. Adulteration and misbranding of amphetamine hydrochloride tablets. U. S. v. Robert Brinton Morris (Uno Laboratories). Plea of not guilty subsequently retracted. Fine of \$100 on count 1; imposition of sentence on count 2 suspended and defendant placed on probation for 2 years. (F. D. C. No. 29452. Sample No. 46720-K.)

INFORMATION FILED: August 8, 1950, District of New Jersey, against Robert Brinton Morris, trading as Uno Laboratories, at Pitman, N. J.

ALLEGED SHIPMENT: On or about May 7, 1949, from the State of New Jersey into the State of West Virginia.

LABEL, IN PART: (One bottle) "N-Methyl Amphetamine HCL (dl-Desoxyephedrine HCL) 10 Mgm. per Tablet"; (remainder of bottles) "Amphetamine HCL Tablets 10 Mgm. per Tablet."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), the tablets each containing 9.64 milligrams of racemic desoxyephedrine hydrochloride and containing no amphetamine hydrochloride had been substituted in whole or in part for tablets each containing 10 milligrams of amphetamine hydrochloride, which the article purported and was represented to be.

Misbranding, Section 502 (a), the label statements "N-Methyl Amphetamine HCL (dl-Desoxyephedrine HCL 10 Mgm. per Tablet" and "Amphetamine HCL Tablets 10 Mgm. per Tablet" were false and misleading since the tablets of the article contained no amphetamine hydrochloride.

DISPOSITION: April 20, 1951. A plea of not guilty having been retracted, the court imposed a fine of \$100 on count 1, suspended the imposition of sentence on count 2, and placed the defendant on probation for 2 years.

3393. Adulteration and misbranding of Conjugestoral tablets. U. S. v. 1 Bottle * * *. (F. D. C. No. 30765. Sample No. 4991-L.)

LIBEL FILED: March 7, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about October 14, 1950, by Corby-Franklin Associates, from New York, N. Y.

PRODUCT: 1 1,000-tablet bottle of *Conjugestoral tablets* at Brighton, Mass.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mgm. of Estrogens in their naturally occurring water soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to the product, which contained less than the stated amount of estrogens.

DISPOSITION: April 23, 1951. Default decree of condemnation and destruction.

3394. Adulteration and misbranding of prophylactics. U. S. v. 42 Cartons * * *. (F. D. C. No. 30759. Sample Nos. 1494-L to 1496-L, incl.)

LIBEL FILED: On or about March 13, 1951, Northern District of Georgia.

*See also No. 3385.

ALLEGED SHIPMENT: On or about September 15, 1950, and January 2, 1951, by the Zenith Drug Sales, Inc., from Philadelphia, Pa.

PRODUCT: 42 cartons of *prophylactics* at Atlanta, Ga. Examination of samples disclosed that 3.95 percent were either dried out and could not be unrolled or contained holes, and therefore were unsuitable for use.

LABEL, IN PART: (Carton) "Zenith Lubri-Pak ½ Gross."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For the prevention of disease" were false and misleading as applied to an article that was either dried out and could not be unrolled or contained holes.

DISPOSITION: April 6, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3395. Misbranding of Bone Food (bone phosphate). U. S. v. 1 Drum, etc.
(F. D. C. No. 30231. Sample No. 81871-K.)

LABEL FILED: November 9, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about August 15, 1950, from Chicago, Ill.

PRODUCT: 1 full drum containing 325 pounds and 1 partly filled drum containing 100 pounds of *bone phosphate*, and 102 1-pound bottles and 98 6½-ounce bottles of the same product relabeled *Bone Food*, at Miami, Fla., in possession of Carothers' Laboratory, together with a number of loose bottle labels, a number of circulars entitled "Carothers' Laboratory To The Physician," and a number of placards entitled "Your Bones Can Be Like This."

Examination showed that the *Bone Food* contained the declared proportion of calcium and phosphorus but less than 1 percent of magnesium.

RESULTS OF INVESTIGATION: The article contained in the bottles was repackaged from one of the above-mentioned drums at the point of destination. The consignee had the labels, circulars, and placards printed, and these circulars and placards were sent to customers with initial shipments of the repackaged product.

LABEL, IN PART: (Drum) "Bone Phosphate"; (bottle) "Carothers' Bone Food #1 Mineral Supplement To Your Diet Analysis: Calcium 33% Phosphorus 15% Magnesium 14% Iron 710 ppm Zinc 30 ppm Copper 5 ppm Manganese 4 ppm Fluorine 400-500 ppm."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the articles in the drums and bottles, namely, the bottle labels, circulars, and placards, contained statements which were false and misleading. The statements represented and suggested that the articles were an adequate and effective treatment for arthritis, bone ailments, rheumatism, tooth and gum disorders, high blood pressure, and low blood pressure; that they were effective to insure the growth of normal, healthy, and strong bones and joints, and healthy nails and teeth; and that they were effective to prevent dental caries, abscesses of the teeth, gum disorders, and death from rheumatic heart disease. The articles were not an adequate and effective treatment for such diseases and conditions, and they were not effective for the purposes stated and implied. The articles were misbranded while held for sale after shipment in interstate commerce.

*See also Nos. 3385, 3388, 3392-3394.